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TITLE: Psychological and Neuropsychological Predictors of Non-Compliance to Mammography Screening Among High-Risk African American Women

PRINCIPAL INVESTIGATOR: Sharon L. Steele

CONTRACTING ORGANIZATION: Howard University
Washington, DC 20059

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Introduction

Research has shown that women with a family history of breast cancer experience high levels of anxiety and intrusive thoughts about the disease and that the distress may disrupt the neuropsychological functioning necessary for engaging in regular screenings. In order to improve use of mammography screening and reduce breast cancer deaths an understanding of the psychological and neuropsychological factors that impact on repeat mammography screenings is essential. The purpose of this research is to evaluate the relationship between psychological distress (anxiety and intrusive thoughts about breast cancer) as well as neuropsychological functioning (executive cognitive functioning) on adherence to repeat use of mammography screenings. To meet the objective, it is proposed that 112 women will be selected as participants, 56 adherers to screening and 56 non-adherers will complete a series of questionnaires evaluating anxiety and intrusive thoughts as well as tests assessing neuropsychological functioning. The scores on the measures will be later analyzed to determine the relationship among anxiety, executive functioning and repeat screening.

BODY Description of Research Accomplishments

This section will describe research accomplishments as they related to the Statement of Work outlined in the grant proposal.

Assemble instruments for study (Months 1-3)

To begin, informed consent was obtained from the Howard University Institutional Review Board (IRB) after the development and submission of the Informed Consent form which was then reviewed, analyzed and subsequently approved by the committee of the Howard University Review Board – the study did not begin until university approval was obtained. Fifty copies of the approved consent form were then used for testing with the first fifty participants. A copy of the approved Informed Consent form is included for review (See Appendix A)

To prepare for the commencement of the study, the psychological instruments (Brief Symptom Inventory and Impact of Event Scale) and neuropsychological instruments (Stroop Test, Wisconsin Card Sorting Task, Peabody Picture Vocabulary Test) were purchased from Psychological Assessment Resources. Copies of the forms (where necessary) were made to be used by the participants of the study.

A flyer outlining the purpose of the study, characteristics of the target population, location of study and contact information of principal investigator was developed and submitted for approval of the Howard University IRB (A copy of the approved flyer is included in Appendix B). The flyer was utilized in the recruitment procedure and included the following: 1) Postings in the Howard University Cancer Center, Howard University Hospital (Department of Radiology, Ambulatory Center, Women's Wellness Clinic, Mammography Center). 2) Submission to local media outlets (Senior Beacon, Washington Informer). 3) Postings as bulletins in local churches and faith-based organizations including: Mt. Pleasant Baptist Church in Washington, DC; Ebenezer

A.M.E Church; Lion of Judah Community Baptist Church; First Baptist Church of Glenarden. 4) Finally, the content of the flyer was presented on local radio stations including (WHUR, WPGC, Magic 102.3, WTOP) (See Appendix C for a copy of a media outlet posting).

Screen and recruit study participants (Months 4-7)

The principal investigator identified first-degree relatives of breast cancer patients by using the following approaches:

- a) Letters were sent to first-degree relatives participating in screening programs at the Howard University Cancer Center.
- b) Flyers were posted throughout the Howard University Hospital including: Howard University Cancer Center, Department of Radiology, Department of Mammography, Outpatient Clinic, and Women's Wellness Center.
- c) Content of the flyer was posted in local print media outlets and this included: Senior Beacon and Washington Informer.
- d) The principal investigator attended and handed out flyers at local health fairs and events that involved a health component and these included:
 - Howard University Cancer Center Partners in Survival workshop
 - 39th Annual Senior Citizen's Day Celebration at First Baptist Church Health Fair
 - The Lion of Judah Community Baptist Church Health Fair
 - Stone Soul Picnic- Magic 102.3
 - Howard University Cancer Center- Mammography Day
 - Ebenezer A.M.E Church Health Fair
 - First Baptist Church of Glenarden Health Fair
 - Howard University International Health Fair

Participants who contacted the principal investigator for permission to participate in the study were screened using the attached form (See Appendix D) in order to ensure that they met eligibility requirements. Eligible prospective participants were invited to the Cancer Center to participate in the study at a scheduled date and time.

Finally, a script was developed for use in conducting the study to ensure consistency in the delivery of information to all participants. (See Appendix E)

Data collection (Months 8-14)

To date, 37 participants were tested and testing entailed the following:

- Completion of informed consent
- Completion of HIPPA form (See appendix F)
- Completion of background questionnaire
- Completion of psychological questionnaires
- Completion of neuropsychological testing
- Debriefing

The result of each participant's performance is kept in individual file folders and locked in a file cabinet in the Howard University Cancer Center.

Key Research Accomplishments

The following lists the key research accomplishments to date:

- Setting up and preparing laboratory for testing including: installing PC version of the neuropsychological test (WCST).
- Development, submission and consequent IRB approved Informed Consent form (See Appendix A)
- The development, submission and consequent IRB-approved recruitment flyer (See Appendix B)
- The development, submission and consequent IRB-approved Protected Health Information for Research Purposes Disclosure form (HIPPA form) (See Appendix F)
- The distribution of approved flyer to local print and aural media outlets (Print: Senior Beacon, Washington Informer; Aural: WPGC radio, WHUR radio, Magic 102.3 radio, WHUT television).
- Recruitment and subsequent testing of thirty-seven, first-degree relatives of breast cancer-diagnosed women.

Reportable Outcomes

- American Association for Cancer Research (AACR) – Minority Scholar Award in Cancer Research. The award was presented to the principal investigator at the 95th annual meeting of the AACR in Orlando Florida, March 27, 2004.

Conclusions

Currently, data is being collected and will be analyzed when all data is collected. At that time summaries and conclusions will be drawn about the research.

References

Not applicable

APPENDIX A

**CONSENT FOR INVESTIGATIVE PROCEDURES
HOWARD UNIVERSITY
WASHINGTON, DC**

You are being asked to participate in the following tests/and procedures, which are needed for the project entitled, "Neurocognitive Functioning and Mammography Screening"

1. Tests and/or Procedures to be administered

Background Questionnaire: assesses social, family and educational background, alcohol and drug history, and family history of breast cancer. (15 minutes to complete)

Brief Symptom Inventory: measures mood state. (5 minutes to complete)

Impact of Event Scale: measures thoughts. (5 minutes to complete)

Peabody Picture Vocabulary Test: measures ability to make word-picture associations. (15 minutes to complete)

Stroop Test: measures attention. (5 minutes to complete)

Wisconsin Card Sorting Task: measures shifting of attention. (30 minutes to complete)

2. Explanation to Subject

This study is conducted by Sharon Steele, a doctoral student in the Department of Psychology and Dr. Adams-Campbell, graduate professor, Howard University Cancer Center. The purpose of the study is to look at neurocognitive functioning (decision-making and shifting attention) of women at risk for breast cancer disease to find out if difficulties in decision-making may explain why some women do not come in for repeat mammography screenings. We know that women at risk for breast cancer sometimes feel anxious about it and the anxiety may cause them to not come for repeat screening. We do not know however, if the anxiety that the women feel may have an impact on decision-making (neurocognitive functioning) and indirectly cause non-adherence (not coming in for screenings).

HOWARD UNIVERSITY
IRB
APPROVAL PERIOD

Initials _____

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Initials _____

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The total amount of time needed for your participation in this study is one hour and fifteen minutes. When you come in, you will first be asked to give us some personal information including: name, years of education, marital status, income, availability of health insurance, history of mammography screening and family history of breast cancer. You will then be given two pen and paper measures that will measure how anxious you feel about breast cancer and how often you think about it. After you finish completing the pen and paper measures you will perform two types of activities. The first will assess your attention and the second will assess how quickly you shift your attention when given a cue. There are no right or wrong answers. It is just important that you do your best and answer the questions as honestly as you can. Both the pen and paper measures and the activities will cause little discomfort and present minimal risk to your physical and mental well-being. However, if at any point you do feel tired you may take a break.

The information that you give us will be kept in confidence. After you complete the surveys your information will be sealed in an envelope. Also, any identifying information such as your name will not be on these envelopes and instead, we will use numbers to identify each participant in the study. No one will have access to this information except the experimenters participating in the study. At the end of the testing you will be reimbursed \$10.00 for travel expenses.

Participation in this experiment will be helpful in order to help us to understand some reasons why some women do not attend mammography screenings and this may help health-care practitioners give more support and resources to clients. You may refuse to participate or withdraw at any time during the session without any further obligations. If you decide to withdraw from the study, simply tell Sharon Steele that you do not wish to continue.

3. Subject's Statement of Understanding

In the event of physical injury resulting from the research procedure, emergency medical treatment will be provided, but financial compensation will not be available.

The tests or procedures for this study involve the completion of questions on surveys which may be novel, but they do not involve any risk(s) other than described in item #2. Your participation in this study is voluntary. All reasonable precautions have and will be taken to reduce risk(s) and to provide you with care.

You are free to withdraw this consent and discontinue participation in this project at any time without affecting either your ability to receive on-going care or your relationship with Howard University Hospital.

Initials _____

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The Howard University Institutional Review Board will have access to the records of this project.

Dr. Adams-Campbell can be reached at (202) 806-7697 in the event that you have any questions regarding your participation in this project. If you have questions at any time that you would like to discuss with someone other than the investigators on this project, you are free to call the office of the Executive Secretary, Institutional Review Board at (202) 806-7818 between 8:30 AM and 5:00 PM or page at 1-800-946-4646. You may also contact Dr. Adams-Campbell at any time about this research and research-related rights. You should contact her in the event of any research-related injury.

I have read the above description of the research project. Anything I did not understand was explained to me by Sharon Steele and I had my questions answered to my satisfaction. I agree to participate in the Neurocognitive Functioning and Mammography Screening project.

I acknowledge that I have received a personal copy of this consent form.

Subject's Name (Print)

Subject's Signature

Date

I, the undersigned, have defined and fully explained the test(s) and procedure(s) involved in this investigation to the above subject.

Signature of Person Obtaining Consent

Date

Initials _____

APPENDIX B

MAR - 5 2004

IRB-02-GSAS-16

Do You Have a Family History of Breast Cancer?

If you have a family history of breast cancer and:

- **Are an African-American female;**
- **Age 40+ years;**
- **Never diagnosed with breast cancer; and,**
- **Have a mother, daughter or sister diagnosed with breast cancer.**

Then we ask you to volunteer for this research study. We want to understand the factors that predict mammography screening so that we can encourage more preventive health care behaviors among at-risk African American women.

The study is conducted daily at the Howard University Cancer Center and involves a one-time visit for approximately 1 hr and 15 minutes.

The study will involve:

- **Completing three questionnaires that ask about family history of breast cancer, screening behaviors and feelings of anxiety;**
- **Completing two psychological tests that assess decision-making and attention.**

Travel reimbursement of \$10.00 is provided.

For more information contact Sharon Steele at 202-865-4615 or email at shapsych98@hotmail.com

APPENDIX C

Health Studies Page

THE PLACE TO LOOK FOR INFORMATION ON AREA CLINICAL TRIALS

Studying breast cancer patients' families

By Barbara Raben

Although African American women have a lower incidence of breast cancer than white women, they die from the disease at a much higher rate. This is primarily due to the fact that the cancer tends to be discovered at a later stage in black women, when it is less treatable.

The five-year breast cancer survival rate in black women is 71 percent, while it is 85 percent for whites. Overall, the death rate is 31

percent for blacks and 25 percent for whites. Researchers at the Howard University Cancer Center are trying to understand why there is such a large racial gap in survival of the disease. The simple answer may be fear of getting tested, according to Sharen Steel, who is the principal investigator in a study examining how women with a close family member with breast cancer handle the stress.

"We are trying to examine to what level

these family members are experiencing stress, and if that anxiety is stopping them from going in for screening themselves," Steel said.

Qualifying for the study

Howard University Cancer Center, adjacent to Howard University Hospital in Northwest Washington, is seeking women of African descent who are 50 to 64 years old for the study. They must never have been diagnosed with breast cancer, but must have a mother, sister or daughter with the disease.

Participants will make one 90-minute visit to the center to take several psychological tests. The tests are designed to measure their stress about cancer and learn how that stress may influence how they make decisions about getting screened for breast cancer themselves.

They will also be asked about their history of getting mammograms over the last five years.

"There's still this myth out there that what you don't know won't hurt you," Steel said. "Some are fearful of what they'll find out if they get screened. Others view get-

ting a mammogram as a painful, cold experience and are reluctant to get one. We want to demystify the process."

The study began in January, and women are being recruited for it through the end of the year. Participants will receive \$10 in compensation for their time.

Although mammograms are not part of the study, women will be encouraged to get screened through their own doctors.

Those without health insurance can get free mammograms and other healthcare through the Cancer Center's Project Wish. Support groups for breast cancer patients and their families are also available.

Other cancer studies, too

In addition, the Cancer Center is seeking women who have breast cancer for two trials examining treatment.

And a breast cancer prevention trial is recruiting women at high risk of breast cancer to study the differences between the drugs tamoxifen and raloxifene in preventing the disease.

For information about any of these studies, or to volunteer, call the Cancer Center at (202) 865-4615.

studying urinary tract disease at the National Institute of Diabetes and Digestive and Kidney Diseases, one of the National

Urinary infections

From page 21

BEACON BITS

ONGOING BEREAVEMENT SUPPORT GROUPS

In Montgomery County, AARP and Holiday Park Senior Center are offering weekly support groups for people who have been widowed for less than two years. Groups meet every Tuesday at 2:30 p.m. or every Thursday at 2 p.m. Holiday Park is located at 3950 Ferrara Drive, Wheaton, Md. For more information or to register, call (301) 949-7398.

In Virginia, HAVEN is offering a support group for anyone who has lost a loved one. Meetings are held on the first and third Wednesday of each month from 7:30 to 9 p.m. at 4806 Ravensworth Rd., Annandale, Va. For more information, call (703) 941-7000 or go to www.havenofhope.org.

CAN'T SLEEP?

Are you ages 65 to 80?

Do you have difficulty sleeping?

Are you otherwise in good health?

You may be eligible to participate in a research study of an investigational medication for

APPENDIX D

Telephone Screening Form

Hello is this Ms. _____?, my name is Sharon Steele and I am calling from the Howard University Cancer Center.

I am calling regarding a study that will be underway here at the Cancer Center and the purpose of the study is to try to understand the reasons why some women obtain regular mammography screenings and why some women do not. We are contacting African-American women who are high risk for breast cancer to invite their participation in the current study.

This phone call is meant to randomly select a sample of women who are considered 'adherers' to repeated mammography screening and 'non-adherers' to repeated mammography screening to come in and participate in the study. Full participation will last for approximately one hour and fifteen minutes. I would like to ask you a couple of questions to determine if you meet the eligibility requirements for participation. Your responses to these questions will be kept strictly confidential.

1. Are you an African-American female?
☐ Yes ☐ No ---- End Interview here
2. What is your current age?
3. What is your date of birth?
4. Do you have at least one first degree relative (mother, sister or daughter) with breast cancer?
☐ Yes ☐ No ----End Interview here
5. Do you speak and read English?
☐ Yes ☐ No ----End Interview here
6. Do you have a previous history of breast cancer?
☐ No ☐ Yes ----End Interview here
7. Have you used substances such as alcohol, or other substances (drugs) within the past 30 days?
☐ No ☐ Yes ----End Interview here
8. When was the date of your last mammogram?
9. How many mammograms have you had?
[If less than 3, group as non-adherer]
[If 3 and more, group as adherer]

I would like to invite you to participate in our study at the Howard University Cancer Center at a time that is convenient for you. There will be no financial compensation for your participation we will however, ensure that you receive a stamped parking pass, which allows you to park freely on site for the length of time that you are here. Your participation will be very instrumental in allowing us to understand the reasons why some women return for mammography screenings and others do not.

We need to schedule you for a specific time to come to the Howard University Cancer Center. You will need to allow for approximately one hour and fifteen minutes.

Can you come to the Cancer Center on _____ AM/PM. On _____,
____/____/____
Time (day of week) MO
Day Year

If you find that you cannot keep the appointment for any reason, please call this number [202-865-4615] and let us know. Did you get that number written down?

We look forward to seeing you. We are located in the Howard University Cancer Center, Room 111, which is located at 2041 Georgia Avenue, on 5th and "V" streets.

Do you have any questions that I may answer for you at this time?

Thank you for your time and cooperation.

APPENDIX E

**Script for 'Psychological and Neuropsychological Predictors of
Mammography Screening' Study**

1. GREETINGS

2. TAKE PERSON TO MEETING ROOM

3. INFORMED CONSENT

The first document in the series of test is the informed consent. Please read carefully, and if you have questions please feel free to ask me. You are required to sign the consent form after having read and understood the items listed.

(After person signs consent, present self-report measures)

4. SELF-REPORT MEASURES

The next series of items are the following: a) background questionnaire to assess family history of breast cancer, education, income and other concerns. The other questionnaires assess anxiety and intrusive thoughts.

Please answer the questions on each questionnaire carefully and note that the questions are in fact printed on both sides of each sheet of paper.

While you fill out the questionnaires I will make a copy of the informed consent for your records.

Are there any questions?

5. COMMENTS

Did you have any question on any of the items printed on the questionnaires?

Yes – answer questions

No – go to neuropsychological testing

We will go downstairs where we will continue the session.

6. NEUROPSYCHOLOGICAL TESTING

Please have a seat

The first test that I will give you will be a simple assessment of your perception of color.

I will hold up five cards, and as I hold up each card, I would like you to tell me the color of the card that you see in front of you.

Ready?

What color is....?

What color is...?

What color is...?

What color is....?

What color is...?

Very good

Now let's begin.

A. Peabody Picture Vocabulary Test

(Go to training item C)

I want to find out how large your vocabulary is.

See, there are four pictures on this page. Each of them is numbered 1, 2, 3, 4.

I will say a word, then I want you to tell me the number of the picture that best tells the meaning of the word. Let's try one. What number is 'parrot'? [2]

Good, let's try another one, what number is scissors? [1]

[Go to training item D]

Now look at the four pictures on this page. What number is mowing? [3]

Good, let's try another one, what number is riding? [2]

[Go to testing items]

Fine, now I am going to show you some other pictures. Each time I say a word, you say the number of the picture that best tells the meaning of the word. As we go through the book, you may not be sure you know the meaning of some of the words, but look carefully at all of the pictures anyway and choose the one you think is right. What number is [Start test item]

B. Stroop

Page 1:

- *This is a test of how fast you can read the words on this page. After I say "begin", you are to read down the columns starting with the first one until you complete it (point to column)*

And then continue without stopping down the remaining columns in order.

If you finish all the columns before I say "stop" then return to the first column and begin again. Remember, do not stop reading until I tell you to "stop" and read out loud as quickly as you can. If you make a mistake, I will say "no" to you. Correct your error and continue without stopping. Are there any questions?

Ready?

Then begin

As the subject says the first response (whether right or wrong) start timing. After 45 seconds say:

"Stop." Circle the item that you are on. If you finish the entire page and began again, put a one by the circle. Turn to the next page.

Page 2:

This is a test of how fast you can name the colors on this page. You will complete this page just as you did the previous page, starting with this first column. Remember to name the colors out loud as quickly as you can.

Time for 45 seconds

Page 3:

This word page is like the page you just finished. I want you to name the color of the ink the words are printed in and ignore the word that is printed in each item.

For example (point to the first item in the first column), this is the first item, what would you say?

If the person is incorrect, say "No, that is the word that is spelled here, I want you to say the color of the ink the word is printed in."

Now, what would you say to this item? (point to the same item)

Good, you will do this page just like the others starting with the first column and then going on to as many columns as you can.

Remember, if you make a mistake, just correct it and go on.

Are there any questions?

Then, begin (begin timing)

Stop. Circle the item you are on.

C. Wisconsin Card Sorting Task

This test is a little unusual because I am not allowed to tell you very much about how to do it. You will be asked to match each of the cards that appear here (point to the response card that appears at the bottom of the screen)...to one of these four key cards (point to each of the stimulus cards at the top of the screen)

On the keyboard in front of you are four symbols which resemble the key cards (point to each of the keyboard keys followed by the symbol card for which it represents). To make a match, simply press the key with the symbol that you believe matches the card at the bottom of the screen (point to the first response card at the bottom center of the screen).

The computer will place your card under the key card that you select and a new card will appear at the bottom of the screen. If you wish to change your answer before the card stops moving, immediately press the key a second time. You will then be permitted to select again.

However, you may not change your answer after the card stops moving. If this happens, don't try to hit another key, just go on to the next card. I cannot tell you how to match the cards, but the computer screen will show you each time whether you are correct or incorrect. The computer will also say the same word that it shows on the screen (correct or incorrect). If you are incorrect, simply try to match the next card correctly until the test is over. There is no time limit on this test.

Are you ready?

Let's begin.

7. END OF TEST

I would like to thank you for participating in the study.

Do you have any questions for me to answer at this time?

Thank you once again for you participation, as a token of our appreciation for your time and effort we would like to offer you \$10.00. Take care and have a great day!

Complete receipt!

APPENDIX F

Form A

Authorization to Use and Disclose

Protected Health Information for Research Purposes

AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

I agree to permit Howard University Cancer Center, my doctors, and my other health care providers, together Sharon L. Steele, and Dr. Lucile L. Adams-Campbell and her staff (together "Researchers"), to use and disclose protected health information about me as described below.

1. The health information that may be used and disclosed includes:

- ☒ all information collected during the research described in the Informed Consent Form for the study "Neurocognitive Functioning and Mammography Screening" Research; and
- ☒ health information in my medical records that is relevant to the Research.

2. The Providers may disclose health information in my medical records to:

- ☒ the Researchers;
- ☒ the sponsor of the Research, The Department of Defense – Breast Cancer Research Program and its agents and contractors ; and
- ☒ representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of research.

3. The Researchers may use and share my health information:

- ☒ among themselves, with the Sponsor, and with other participating researchers to conduct the Research; and
- ☒ as permitted by the Informed Consent Form.

4. The Sponsor may use and share my health information as permitted by the Informed Consent Form.

5. Once my health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure.

6. Please note that:

- ☒ You do not have to sign this Authorization, but if you do not, you may not participate in the Research.
- ☒ You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must write to the HIPAA Privacy Officer, Office of the Chief Compliance Officer for Health Affairs; Howard University Hospital, 2041 Georgia Avenue, N.W., Ste. 2066; Washington, D.C. 20060. However, if you revoke this Authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this Authorization, the Providers, Researchers and the Sponsor may

continue to use and disclose the information they have already collected to protect the integrity of the research or as permitted by the Informed Consent Form.

- X While the Research is in progress, you will not be allowed to see your health information that is created or collected by the Howard University Cancer Center in the course of the Research. After the Research is finished, however, you may see this information as described in Howard University Health Sciences' Notice of Privacy Practices.

7. This Authorization does not have an expiration (ending) date.

8. You will be given a copy of this Authorization after you have signed it.

Signature of participant or participant's legal
representative

Date

Printed name of participant
(if applicable)

Printed name of legal representative

Representative's relationship to participant